

REMARKS

The rejection has been considered at length. However, for the reasons set forth below, it is believed that the claimed subject matter would not have been rendered obvious by the combination of the cited references.

Claims 10-12 and 14-18 are pending and claims 10 and 11 have been amended hereinabove. Support for amended claim 10 can be found in the specification, page 19, table 11. Claim 11 has been amended to correct a minor typographical error. No new matter has been added.

Claims 10-12 and 14-18 are rejected under 35 U.S.C. § 103(a) as being obvious over Cavazza (US Patent No. 4,474,812, hereinafter ('812')), Cavazza (US Patent No. 6,245,378, hereinafter ('378)) and De Felice (US Patent No. 3,830,931, hereinafter ('931)) in view of De Simone (US Patent No. 6,037,373, hereinafter ('373)) and Xiu (US Patent No. 6,399,116, hereinafter ('116)).

Applicants respectfully traverse the rejection.

The presently claimed invention is directed to a method for treating disorders caused by andropause by administering a combination of propionyl L-carnitine and acetyl L-carnitine. The improvement over the prior art is that the administration of the claimed combination does not cause any increase in the blood level of testosterone (*e.g.*, page 19, table 11).

'812 does not disclose Applicants' invention. '812 only provides for a novel use of compositions comprising L-carnitine for improving biochemical and behavioral parameters peculiar to senility (*e.g.*, col. 1, lines 29-33). The parameters disclosed in '812 are motor activity, triglycerides in heart, liver and tibial muscle, cardiac performance etc (*e.g.*, throughout the disclosure). However, '812 is completely silent with regards to the presently claimed method to

treat disorders related to andropause, such as reduced libido or sexual drive and reduced quality of erection, depression of mood and fatigue, which does not induce any increase of testosterone blood level. As such, '812 does not disclose all of the claimed limitation and therefore does not render obvious the claimed subject matter.

'378 does not provide the missing link in that it suffers from the same deficiencies. Specifically, '378 discloses a combination of "carnitines" as the basic active ingredients of a nutritional supplement (*e.g.*, col. 1, lines 9-14). '378 is also completely silent with regards to a method to treat disorders caused by andropause without increasing the blood level of testosterone as claimed herein. Accordingly, as '812 above, '378 either alone or in combination with '812, fails to disclose all of the claimed limitations and fails to render obvious the claimed subject matter.

'931 as well does not provide for the missing link and suffers from the same deficiencies of '812 and '378. Specifically, '931 only provides for methods for improving myocardial contractility and systolic rhythm by administering carnitine (*e.g.*, col. 1, lines 37-42). In addition, as the references described above, '931 as well is completely silent with regards to the presently claimed method for treating disorders caused by andropause. As such, '931 as well does not disclose all of the claimed limitations and would not have render obvious the claimed subject matter either alone or in combination of '812 and/or '378.

'373 does not provide any missing links because it suffers from the same deficiencies as the references discussed above. Specifically, '373 discloses that carnitines are capable of increasing the level of IGF-1 (insulin-like growth factor-1) in human biological fluids (*e.g.*, col. 2, lines 45-55). The increased levels of IGF-1 is useful for the treatment of IGF-1 related diseases such as neuropathies of the optic nerve, neuralgia of the trigeminal nerve, Bell's paralysis, chronic hepatic necrosis etc (*e.g.*, the abstract and col. 4, lines 2-22). As such, '373 does not provide any

disclosure on a method for treating disorders caused by andropause by administering carnitines without causing an increase in blood level of testosterone. '373 is completely silent with regard to disorders caused by andropause and with regard to methods for treating it. Accordingly, '373 does not disclose the claimed limitations and it also would not have rendered obvious the claimed subject matter, either alone or in combination with either one or all of the references discussed above.

Finally, '116 only provides for administration of a preparation comprising *Rhodiola crenulata* to treat a variety of ailments (e.g., col. 1, lines 5-24). '116 describes that one of the activities of *Rhodiola crenulata* comprises a method of increasing the testosterone levels in a host in need thereof (e.g., col. 4, lines 43-46). As such, '116 teaches away from the presently claimed invention. That is, the presently claimed method comprises the administration of a composition which does not increase testosterone blood levels, while '116 teaches exactly the opposite.

Accordingly, the combination of any of the references discussed above with '116 would result in a method in which the composition would increase the testosterone levels. This is not what is claimed in claims 10-12 and 14-18. As such, it is respectfully submitted that the Examiner's combination of '812, '378, '931 in view of '373 and '116 would not have rendered obvious the claimed subject matter to one skilled in the art.

As such, Applicants respectfully submit that the subject matter of pending claims 10-12 and 14-18 is allowable over the combination of the cited references and a Notice to that effect is respectfully requested.

This response is being filed within the shortened statutory period for response, thus, no fees are believed to be due. If, on the other hand, it is determined that further fees are necessary or any overpayment has been made, the Commissioner is hereby authorized to debit or credit such sum to

Deposit Account No. 02-2275.

Pursuant to 37 C.F.R. § 1.136(a), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time of its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated herewith is to be charged to the above-mentioned deposit account.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted

Date: July 30, 2009

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